

In the United States Court of Federal Claims

No. 98-317 V

(Filed March 5, 2003)

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LENA MARIE TEBCHERANI, by her  
father, ELIAS TEBCHERANI,  
Petitioner,

v.

SECRETARY OF THE DEPARTMENT  
HEALTH AND HUMAN SERVICES,  
Respondent.

Vaccine Act; Remand;  
Harmless Error;  
Reversible Error;  
Failure to Consider  
Evidence; Significant  
Aggravation of  
Possible Symptoms  
of Autism.

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*Elias Tebcherani*, Pro Se, San Diego, California, for petitioner.

*Tami C. Parker*, Department of Justice, Washington, D.C., with whom was *Assistant Attorney General* Robert D. McCallum, Jr., for respondent. *John Lodge Euler*, Acting Director, *Mark W. Rogers*, Acting Deputy Director, *Vincent J. Matanoski*, Acting Assistant Director.

**ORDER**

Petitioner, Elias Tebcherani, acting on behalf of his daughter, Lena Tebcherani, seeks review of the Special Master’s denial of compensation under the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”). See 42 U.S.C. §§ 300aa-11 to -34 (2000). For the reasons stated below, it is concluded that this matter is to be remanded to the Special Master in accordance with the court’s instructions, detailed herein, pursuant to 42 U.S.C. § 300aa-12(e)(2)(C).

## BACKGROUND

### Factual History

The facts of this matter have already been set forth in detail in the order issued on March 21, 2001. Only the facts sufficient for an understanding of the issues that give rise to the matters currently before the court for consideration will be discussed.

### Procedural History

#### a. Proceedings Before the Special Master

On or about October 6, 1999, an evidentiary hearing was conducted in this matter, the scope of which was limited to the factual issue of whether the onset of symptoms alleged by petitioners occurred within 72 hours of vaccination, such that petitioner might be able to establish an injury described in the Vaccine Injury Table (“Table”) set forth at 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3(a);<sup>\1</sup> Transcript of Evidentiary Hearing conducted on Oct. 6, 1999 (“Tr.”) at 5.

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<sup>\1</sup> Pursuant to Congressional authority, set forth at 42 U.S.C. § 300aa-14(c), the Table, and the accompanying “Qualifications and aids to interpretation,” codified at 42 U.S.C. § 300aa-14(a) & (b), have been revised by the Secretary of the Department of Health and Human Services. See National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table - - II, 62 Fed. Reg. 7685, 7688 (1997) (codified at 42 C.F.R. pt. 100); see also *Terran v. Secretary of HHS*, 195 F.3d 1302, 1314 (Fed. Cir. 1999) (determining that 42 U.S.C. § 300aa-14(c) does not violate the Presentment Clause of the United States Constitution), *cert. denied*, 531 U.S. 812 (2000); *O’Connell v. Shalala*, 79 F.3d 170, 176-77 (1<sup>st</sup> Cir. 1996) (determining that revisions set forth in National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table - - II were permissible); *Perez v. Secretary of HHS*, No. 00-328V, 2003 WL 431593, n.3 (Fed. Cl., Spec. Mastr. Jan. 14, 2003) (noting statutory history). Accordingly, all references to the Table shall include citation to the applicable revisions contained in the regulation.

At that hearing, testimony was elicited from Lena's parents as well as from Lena's treating pediatrician, Dr. Narayan. Upon hearing the testimony, the Special Master stated his concerns about "the imprecision and inconsistencies of the parental testimony." Tr. at 122; *see* Decision, filed March 27, 2001, ("Onset Decision") at 3. In particular, the Special Master focused upon the fact that although both parents were confident that the vaccine was administered on March 31, 1995, neither parent seemed certain of which day of the week that date fell upon. In this regard, the Special Master noted that imprecision in Mrs. Tebcherani's testimony made it difficult to understand what she meant when she testified that on the "second" day after receiving the DaPT vaccination Lena returned to preschool and that her teachers purportedly noticed a change in her behavior. Tr. at 21; 25-27.

The Special Master took judicial notice of the fact that March 31, 1995 was a Friday. Tr. at 46. He further noted that according to Mrs. Tebcherani, Lena attended school three days each week: on Mondays, Wednesdays and Fridays. Tr. at 44. The Special Master also noted that if Mrs. Tebcherani's testimony were to be believed, and if it were determined that the next day that Lena attended school was Monday, April 3, 1995, petitioner might establish that Lena exhibited symptoms within the 72 hour period required for a Table injury. Tr. at 119. The Special Master was troubled, however, by the apparently contradictory testimony of Mr. Tebcherani, who testified that Lena attended preschool on Tuesdays and Thursdays. Tr. 79.

Specifically, the Special Master stated that:

We then have the vaccination with any inconsistent or imprecise parental recollections of what day of the week and what time it occurs and then some imprecision as to what happens in the immediate couple of days after that. Since the mother's recollection was that the next day she took her to the preschool and at the preschool they noted some issues, some matters, some problems, not eating well, seemed to be fussy, to put it in a nutshell, and then the day after that other matters were noted.

If you carry that to the mother's imprecision of the date, that is the day of the week, I should say, and if it was Friday, the next day according to the mother that the child would have gone to the preschool was Monday, which is now right on the edge or 72 hours, . . . if the father's recollection is correct and it was a Tuesday, Thursday attendance at the preschool, then . . . whatever happens at the school that's noted would be off table if the Court accepts that at all. That would become off table.

So we have interesting inconsistencies and imperfections and the [c]ourt is concerned about that. And what we do have even if one accepts the mother's testimony is essentially some crying, some fussiness, presumable [sic] no fever, eating and sleeping alterations and then several days later which she wanted to place as just off of 72 hours would be eye twitching, some rocking behavior and the [c]ourt has lived out that these things are ominous but then when we look at the records themselves, we see that there seems to be at best a one week post-vaccinal [sic] when these events appear to occur and perhaps as long as several weeks . . .

Tr. 118-22.

Nevertheless, the Special Master indicated that based upon the testimony presented, he had "difficult[y] accepting anything more than perhaps a general fussiness within 72 hours and then after that . . . a cascade of [neurological] problems, all of which are reflected in the medical records." Tr. at 122. The Special Master attributed his impression of the case to "the imprecision and inconsistencies of the parental testimony and in particular when . . . [the court] contrasts -- when it juxtaposes [such testimony] . . . with the contemporaneous records and . . . after hearing the testimony of the treating pediatrician, Dr. Narayan . . ." Tr. at 122. Further, the Special Master stated that the medical records and the testimony indicated that Lena suffered "neurological problems prior to the vaccination . . . [both] at birth and

indications possibly in October . . . [19]94 and then certainly a cascade of neurological problems . . . following the vaccination [however,] . . . the [c]ourt cannot say that there is evidence in the contemporaneous records or through parental testimony that the [c]ourt can rely on by preponderance of the evidence [to establish that those symptoms] . . . occur[ed] within 72 hours of the vaccination.” Tr. at 123. Finally, the Special Master said that although there was no “question that in some fashion, Lena has some variation of encephalopathy today, . . . in terms of its onset or its significant aggravation, this [c]ourt does not opine at this moment.” Tr. at 123. Based upon the Special Master’s initial impressions of the evidence submitted, petitioners were ordered to advise the court, within one month of the hearing date, as to whether they would further pursue the matter, presumably via a causation-in-fact theory. Tr. at 125.

#### **b. Remand to Special Master after Review by Court of Federal Claims**

Subsequently, it appears that petitioner and petitioner’s attorney entered into an unconventional arrangement whereby petitioner’s counsel remained in control of the case, but made Mr. Tebcherani responsible for retaining an expert. Petitioner’s counsel later withdrew as attorney of record in the matter.<sup>2</sup> Although it is undisputed that

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<sup>2</sup>On June 29, 2001, the Special Master granted a motion by petitioner’s former counsel, Ronald Homer, Esq., filed on January 19, 2001, which was styled as a Motion to Intervene for Attorney’s Fees and Costs. The Special Master noted that Mr. Tebcherani had indicated he had “absolutely no objection” to the filing by petitioner’s former counsel, and noted that “Mr. Tebcherani intentionally and knowingly waived the attorney-client privilege to the extent that it applies to Mr. Homer’s fees and costs.” See, Order signed by the Special Master, filed June 29, 2001, at 1. Subsequently, Mr. Tebcherani filed an affidavit in which he stated that he had no objection to the filing of “Petitioner’s Former Law Firm’s Application for Fees and Costs filed November 16, 2001.” See Affidavit of Elias Tebcherani, signed January 14, 2002. The record does not include the November 16, 2001 filing referred to in Mr. Tebcherani’s January 14, 2001 affidavit. However, Mr. Homer, petitioner’s former counsel, did file, on January 23, 2002, a document styled as “Petitioner’s  
(continued...)

petitioner was somewhat delayed in retaining an expert witness, the record did not clearly reflect effective communication of the deadlines, established by the Special Master, to petitioner, in his *pro se* capacity, or through Mr. Tebcherani's attorney. Accordingly, following the Special Master's dismissal of the matter resulting from a failure to prosecute, pursuant to Vaccine Rule 21, petitioner's motion for review resulted in the matter being remanded to the Special Master by Order filed March 21, 2001.

With regard to the concerns voiced by the Special Master as to whether Lena attended school within the 72 hour period following the vaccination on March 31, 1995, this court specifically noted that there was some evidence that she did attend on Monday, April 3, 1995. *See* Order, filed March 21, 2001 at 20, n.10. The court further observed that Special Master had asserted at the October 6, 1999 Evidentiary Hearing, that if there were evidence that Lena went to school on the Monday following the vaccination, the Special Master would consider that to be "right on the edge . . . [of] 72 hours." Tr. at 119. Upon review of the record, this Court specifically noted that "after reviewing the school records submitted, [the Special Master may] find that all of the dates upon which Lena was absent from school were either Mondays, Wednesdays or Fridays, and may ultimately conclude that she attended school on that schedule. Lena appears not to have had a recorded absence from school on the Monday following the vaccination." *See* Order, filed March 21, 2001, n.10; *see also* Pet'r Ex. 19. Moreover, it was also pointed out that "there is no indication that the school was closed on that day."<sup>3</sup> *See* Order issued March 21, 2001, n.10.

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<sup>2</sup>(...continued)

Former Law Firm's Application for Fees and Costs," which remains pending at this time.

<sup>3</sup>The attendance records include some information regarding school closings. Specifically, the attendance records demonstrate that the school was closed for a spring vacation, which apparently occurred the week of April 10, 1995 through April 14, 1995, the second week following Lena's reported return to school. *See* Pet'r Ex. 19.

### c. Proceedings Before the Special Master Following Remand

The Special Master apparently disregarded this court's suggestion that the evidence demonstrated that Lena likely did attend school on Monday, April 3, 1995. Accordingly, without further consideration of the evidence presented, by Order filed March 27, 2001, the Special Master issued a determination in which he referred to the statements on the record at the October 6, 1999 evidentiary hearing as a "bench ruling." *See* Onset Decision at 1-2.<sup>4</sup> The Special Master also indicated that he 'affirmed' his October 6, 1999 determination,<sup>5</sup> and concluded that petitioner was unable to establish injuries within the time frame that would qualify as a Table injury. By separate order, filed on the same day, the Special Master specifically outlined the format of the qualified

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<sup>4</sup>The Special Master issued a decision filed March 27, 2001, in which he denied petitioner's claim for compensation on the basis that the evidence did not support an on-table injury. By Order filed March 29, 2001, the Special Master amended the March 27, 2001 Order to remove one line of text. Then, on June 29, 2001, the Special Master issued another version of the March 27, 2001 Order, as amended by the March 29, 2001 Order, in which the citations to the record were conformed to the hard copy version of the transcript of the October 6, 1999 evidentiary hearing.

<sup>5</sup>The statement that the Special Master affirmed the determination made at the Evidentiary Hearing is somewhat confusing because the Special Master specifically noted at that proceeding that:

I don't think there's any question that in some fashion, Lena has some variation of encephalopathy today, presumably from the records *but in terms of its onset or its significant aggravation, this Court does not opine at this moment.*

Tr. at 129 (emphasis added).

Accordingly, although it appears that the intended purpose of the Special Master's March 27, 2001 Order was to affirm a determination that petitioner had failed to prove the onset of Lena's injuries within 72 hours of the DaPT vaccination, it is not clear from the record that that determination was made at the October 6, 1999 hearing.

medical expert's report he required of petitioner in order to demonstrate causation-in-fact.

### **(1) Petitioner's First Medical Expert Report**

In accordance with the orders of the Special Master, petitioner provided the court with an expert report, prepared by Dr. Thomas A. Schweller, M.D., filed May 14, 2001. In Dr. Schweller's opinion, there was "no alternate explanation for . . . [Lena's] condition other than related to the immunization." See Expert Report by Dr. Schweller, ("Schweller Report #1") filed May 14, 2001, at 5. He explained that based upon the medical history provided by Lena's parents and her treating pediatrician, Dr. Narayan, prior to immunization "there was no evidence of unusual development." See Schweller Report #1 at 3. The only exception noted by Dr. Schweller was "an event which may have been related to asphyxia at birth as well as a hydrops condition."6

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6As stated in the March 21, 2000 Order, at birth, Lena suffered profound asphyxia and was resuscitated with endotracheal intubation with 100% oxygen via hand ventilation and administration of epinephrine. Lena was also born with hydrops fetalis, a condition characterized by an abnormal accumulation of serous fluid in the fetal tissues. After birth, Lena suffered a tonic seizure which resulted in severe bradycardia and deep cyanosis. The infant was treated with phenobarbital, to control the seizures, and epinephrine, to bring her heart rate up to normal and was transported, *in extremis*, to Children's Hospital and Health Center ("Children's HHC"), in San Diego, California. See Pet'r Ex. 4-1; see also Order, filed March 21, 2001 at 2.

Soon after arrival at Children's HHC, Lena suffered a gross tonic seizure followed by a period of agitation and was treated with phenobarbital and morphine. Pet'r Ex. 4-1. Lena was hospitalized at Children's HHC for a little more than a month, during which time her condition reportedly improved. Pet'r Ex. 4-11-13. Notably, the medical records indicate that the results of a series of electroencephalogram exams taken over the course of her month long hospital stay, showed evidence of normalization. Pet'r Ex. 4 -12. On November 28, 1990, Lena was discharged to home with her parents, and it was recommended that she continue treatment with phenobarbital. Pet'r Ex. 4-12. It was further recommended that Lena be seen by her pediatrician, Uma Narayan, M.D., one week after discharge, and that she follow up with Hematology, Neurology and Ophthalmological specialists at (continued...)

However, Dr. Schweller opined, when the problem of fluid balance associated with the hydrops resolved, the seizures suffered by Lena at birth also resolved. In Dr. Schweller's opinion, "[t]his would certainly be consistent with a metabolic condition and seizures that resolved without any sequelae." *See Schweller Report #1 at 3.* Dr. Schweller also addressed the strabismus condition Lena suffered during her first year of life which he described as "a common condition often with a genetic component and of no demonstrable relationship to any of the birth difficulties." *See Schweller Report #1 at 3.* Nevertheless, Dr. Schweller opined that prior to the vaccination both the hydrops disorder and the strabismus condition were resolved and during the time immediately prior to the administration of the DaPT immunization, on March 31, 1995, Lena was developing normally.

Dr. Schweller stated that after having examined Lena, he agreed with her clinical diagnosis, as set forth in medical records filed July 18, 1995 and August 22, 1995, of mild to moderate mental retardation, in addition to the more precise diagnosis contained in the medical records filed October 9, 1997, of a developmental evaluation suggesting a childhood disintegration disorder and autistic behaviors, with accompanied mental retardation. *See Schweller Report #1 at 4.*

Dr. Schweller noted that several pediatric neurologists have attempted to define the exact nature of Lena's disorder and that no definable abnormality has been found. Specifically, according to Dr. Schweller, there is no evidence of a metabolic degenerative disorder, any abnormality of chromosomes or mitochondrial disease. *See Schweller Report #1 at 3.* Moreover, Dr. Schweller noted his disagreement with findings of one of Lena's treating pediatric neurologists, Dr. Haas, who determined there were some abnormalities present, based upon his review of an MRI filed July 18, 1996. *See Schweller Report #1 at 5.* Dr. Schweller opined that it is difficult to determine whether the abnormalities noted by Dr. Haas are of clinical significance or whether

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Children's within one month following hospital discharge. *See Pet'r Ex. 4-13; see also Order, filed March 21, 2000 at 2.*

they reflect Lena's early history of perinatal asphyxia and are unrelated to Lena's current clinical state. *See* Schweller Report #1 at 3. Dr. Schweller concluded that he does not agree with Dr. Haas' opinion that the MRI is diagnostic of significant atrophy. *See* Schweller Report #1 at 3.

With regard to the speculation that Lena suffered a viral infection prior to the immunization, Dr. Schweller opined that the medical records do not support a finding of a febrile condition which might support an infectious disease process. *See* Schweller Report #1 at 4. In Dr. Schweller's opinion, Lena was developing normally until the March 31, 1995 administration of the DaPT vaccination. After that vaccine was administered, Dr. Schweller notes there was a marked change in Lena's condition, exhibited by "a change in personality, change in ability to communicate, and a change in the way that the child interacts." *See* Schweller Report #1 at 3. Dr. Schweller concluded that "[there is no evidence for [sic] a degenerative disorder and no alternate explanation for . . . [Lena]'s condition other than related to the immunization and the child has at this point a non-progressive chronic encephalopathy that appeared to be triggered by the . . . [DaPT] immunization [administered on March 31, 1995]. *See* Schweller Report #1 at 4-5.

Finally, Dr. Schweller noted that with regard to the issue of how long after the vaccination Lena manifested symptoms, he relied upon the history as it was provided by Lena's parents in combination with the medical records in order to formulate his conclusions. *See* Schweller Report #1 at 5. Additionally, after reviewing the initial decision of the Special Master, he thought it might be helpful to question any other available fact witnesses who might be able to corroborate the parents' testimony about the onset of Lena's abnormalities. *See* Schweller Report #1 at 5.

In closing, Dr. Schweller qualified his opinion by stating that it has been his experience that families are often unsophisticated about the nature of normal and abnormal behavior as it arises and are inclined to deny abnormalities that evolve with the hope that it is a normal reaction to an immunization rather than a sign of more ominous difficulty. *See*

Schweller Report #1 at 5. Dr. Schweller further noted that he has observed that at times the notations of pediatricians are not supportive of an onset of encephalopathy of a slow development until the parents present to the office again noting the more dramatic elements of the change in personality when it becomes more obvious that their child is not improving. *See* Schweller Report #1 at 5.

## **(2) Petitioner’s Second Medical Expert Report**

On June 11, 2001, the Special Master issued an Order in which he directed petitioner to file an expert medical report to replace the May 1, 2001 medical expert report by Dr. Schweller.<sup>\7</sup> *See* Order, signed by the Special Master, filed June 11, 2001, at 1. The Special Master noted that by his request he intended to direct petitioner’s medical expert to base his conclusions only upon the medical records filed in the case and the October 6, 1999 hearing, “to the extent that those documents are not contradicted or inconsistent with the 27 March 2001 fact decision.” *Id.* at 2.

Accordingly, on July 25, 2001, petitioner’s expert Dr. Schweller, provided the court with a second expert report. In that report, Dr. Schweller stated that pursuant to the Special Master’s request, he was providing clarification of the initial medical report concerning Lena Marie Tebcherani. *See* Expert Report by Dr. Schweller, filed July 25, 2001 (“Schweller Report #2”) at 1. Dr. Schweller explained that he had

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<sup>\7</sup>On May 24, 2001, the Special Master issued an Order in which he opined that Dr. Schweller either “did not understand the [c]ourt’s March 27, 1999 Order or that the order itself was . . . not clear.” *See* Special Master’s Order, filed May 24, 2001, at 1. The Special Master required petitioner’s expert to provide two additional expert medical reports. *Id.* at 2. The first of these additional reports was to provide an opinion limited in scope to the facts contained in the March 29, 2001 fact decision utilizing the medical records filed in this case and the October 6, 1999 hearing transcript. *Id.* at 2. The second expert report was to provide an opinion utilizing “facts not found by the [c]ourt in the March 29, 2001 fact decision.” *Id.* at 3. In that second expert opinion, the Special Master indicated that Dr. Schweller “must set out the facts he thinks are appropriate and explain why he distinguishes or disagrees with the Court’s finding of facts. *Id.* By Order filed June 1, 2001, the Special Master subsequently vacated the March 27, 2001 and May 24, 2001 Orders which directed petitioner’s medical expert to provide the two opinions referenced above.

reviewed: (1) the Special Master's March 27, 2001 determination; (2) the medical records filed in this case; (3) the entire transcript of the October 6, 1999 hearing; and (4) the Vaccine Act.

Dr. Schweller repeated his conclusion, stated in the May 1, 2001 expert report, that "there is no evidence that any of the illnesses suffered by . . . [Lena] in the perinatal period in any way are responsible for . . . [Lena]'s current condition." *See Schweller Report #2 at 1.* Specifically, Dr. Schweller opined that the injuries that persist constitute a disorder of language and interaction that reflect autistic spectrum disorders. *See Schweller Report #2 at 2.*

He further asserted that, given the history provided by the Tebcherani family as well as Lena's treating pediatrician, Lena developed normally until the administration of the DaPT immunization on March 31, 1995. Further, because no one has yet been able to explain the exact pathophysiology of Lena's neurodevelopmental disorder, which purportedly became evident for the first time following the administration of the DaPT vaccine, he believes that Lena's current condition meets the definition of chronic encephalopathy that has persisted and not returned to a baseline status for more than six months. *See Schweller Report #2 at 1-2.* However, as in his May 1, 2001 medical expert report, Dr. Schweller qualified his determination by noting that the early onset of chronic encephalopathy may be subtle and may be difficult to define when there is not a dramatic or violent reaction to a traumatic agent. *See Schweller Report #2 at 3.*

With regard to the question of the timing of the onset of Lena's neurological condition, Dr. Schweller asserted that the determination "is dependent upon the believability of the history as provided by . . . [Lena's] parents as the primary caretakers . . . and secondarily corroborated by the pediatrician's medical records." *See Schweller Report #2 at 2.* In that regard, Dr. Schweller noted that "[t]he family consistently has provided a change in this child's medical condition provoked at the time of the DtaP [sic] immunization." *See Schweller Report #2 at 2.*

### **(3) Respondent's Medical Expert Report**

On August 30, 2001, respondent filed its Medical Expert Report, prepared by Dr. John T. MacDonald, M.D. After summarizing the data contained in the medical records, Dr. MacDonald noted that Lena carries a diagnosis of pervasive developmental disorder, also known as autistic spectrum disorder. In Dr. MacDonald's opinion, Lena's autism is not related to the DaPT vaccination administered on March 31, 1995, but rather, stems from the hydrops fetalis with perinatal asphyxia, she suffered at birth. *See* Expert Report by Dr. MacDonald, filed August 22, 2001 ("MacDonald Report"), at 5.

To reach these conclusions, Dr. MacDonald relied upon several published studies, including one from 1975, in which it was determined that neonatal complications are much more frequently observed in autistic children than in non-autistic children. *See* MacDonald Report at 4. Dr. MacDonald acknowledged that Lena's medical records do not present evidence of a progressive disorder, but did note that her medical records may reflect certain symptoms of autism including difficulties with social interaction, communication skills, and ability to function in normal surroundings. *See* MacDonald Report at 3. In that regard, Dr. MacDonald specifically points out that upon reviewing the medical records, Lena appears to have had at least two recorded instances of uncooperative behavior, both with regard to hearing tests attempted in her pediatrician's office. The tests were attempted when Lena was three years old and again when she was four years old, but could not be accomplished because she was non-compliant. Moreover, Lena's medical history indicates that at an office visit on October 27, 1994, she refused to wear her eye glasses and would neither speak nor communicate with her pediatrician, Dr. Narayan. Pet'r Ex. 6-45. Dr. MacDonald found it particularly noteworthy that the medical records show that Dr. Narayan noted, at that same office visit, that Lena exhibited "very poor eye contact," which he stated was a cardinal sign in autistic individuals along with poor verbal interaction with outsiders. *See* MacDonald Report at 4; *see also* Pet'r Ex. 6-45.

Moreover, Dr. MacDonald notes, as does Dr. Schweller, that children with autism present with a variety of symptoms that can be missed by both the parents and physician and that early recognition, particularly in children younger than four years of age,<sup>\8</sup> is difficult since parents and doctors may not recognize specific symptoms relating to social interaction or may underestimate the significance of such symptoms. *See* MacDonald Report at 4.

In addition, Dr. MacDonald remarked that with regard to the timing of the symptoms Lena suffered, shortly after the vaccine was administered, she exhibited a change in her behavior, characterized by a loss of language ability and emotional upset, noted by her parents, and that she also suffered a viral illness. Dr. MacDonald stated that it was not clear that Lena suffered an acute encephalopathy as defined medically or on the Table and there was no associated major change documented in her motor status, focal neurological signs, or seizure activity. In support of this determination, Dr. MacDonald noted that Lena did not seek medical treatment until April 19, 1995, approximately two weeks after the vaccine was administered. Further, the results of an EEG exam conducted on May 5, 1995 were normal. *See* Pet'r Ex. 6-55. Nevertheless, Dr. MacDonald explained that fluctuations in behavior are typically reported in young autistic children and in many cases it is suspected that this represents a regression, which is actually a short term change in behavior and developmental skills. Furthermore, Dr. MacDonald asserts that rather than being representative of a worsening of the underlying disorder, these incidents are a means of bringing the child to medical attention for further diagnosis.

Dr. MacDonald criticizes Dr. Schweller's theory of causation as seeming to rely solely on the parents' version of Lena's medical history rather than the medical records. Dr. MacDonald further states that even if her parents' version of Lena's medical history were accepted, there is no indication of an acute encephalopathy or any other vaccine related encephalopathy. Finally, Dr. MacDonald points out that his opinion differs from that provided by petitioner's medical expert, largely

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<sup>\8</sup>At the time of the vaccination Lena was approximately four and a half years old.

because, in Dr. MacDonald's view, Dr. Schweller's opinion minimizes the significance of Lena's perinatal ordeal with hydrops fetalis and Dr. MacDonald believes that the neonatal encephalopathy was a causative factor of Lena's autism.

#### **d. The Special Master's Decision**

On September 18, 2001, respondent filed a Motion for Decision on the Record in which the government sought a determination of the matter based upon the written filings without an evidentiary hearing. Petitioner did not respond to the government's motion.

During a telephonic status conference, conducted on October 2, 2001, petitioner asserted that his continued theory of the case is that Lena suffered a compensable injury which manifested itself within the time period set forth in the Table. *See* Order, signed by the Special Master, filed October 2, 2001. This point was significant because petitioner objected to an alleged "inference" by the government that the Tebcheranis were unable to demonstrate causation-in-fact in this case.

On January 29, 2002, petitioner filed his closing arguments, in writing. Respondent's closing arguments were subsequently filed on February 8, 2002. On March 11, 2002, petitioner filed a document styled as "Petitioner's Response to Respondent's Closing Arguments."

On April 5, 2002, the Special Master issued an Entitlement Decision in this case denying compensation. He concluded that based upon his March 27, 2001 onset decision, the facts of this matter do not favor classification of petitioner's injury as a Table injury. He further determined that based upon the evidence presented, petitioner had failed to establish, by a preponderance of the evidence, that the DaPT vaccine caused Lena's injuries in this case.

Before addressing the medical expert testimony, the Special Master set forth the standards necessary for compensation and explained that the Tebcherani family should not assume that Lena's condition is their fault, but rather should realize that sometimes "the issue of

causation is illusive for any number of reasons, not the least of which includes the progress of medical science.” *See* Entitlement Decision, filed April 5, 2002 (“Entitlement Decision”), at 5.

The Special Master then considered each of the two opinions rendered by petitioner’s expert, Dr. Schweller, as well as the opinion offered by respondent’s expert, Dr. MacDonald. The Special Master found the expert report provided by Dr. MacDonald to be more persuasive. Accordingly, the Special Master gave greater weight to Dr. MacDonald’s expert opinion than to that submitted by Dr. Schweller.

In this regard, the Special Master explained that he required petitioner to provide two expert opinions because in his first expert opinion, Dr. Schweller failed to limit his opinion to the facts found by the Special Master. Specifically, the Special Master opined that Dr. Schweller had improperly based his opinion on the parental testimony rather than upon the facts established in the Special Master’s Onset Decision. In particular, the Special Master noted that Dr. Schweller had suggested that the parents’ recollection might have been bolstered by additional fact witnesses who could corroborate Mr. and Mrs. Tebcherani’s testimony because, in Dr. Schweller’s experience, “the notations of pediatricians are not supportive of an onset of encephalopathy of a slow development until the parents present to the office again, noting the more dramatic elements of the change in personality when it becomes more obvious that their child is not improving.” *See* Entitlement Decision at 6. The Special Master contends that Dr. Schweller subsequently contradicted himself by relying upon the pediatrician’s records in conjunction with the parent’s testimony to reach the conclusion that the vaccine caused Lena’s disorder. The Special Master found that the parents’ testimony conflicts with the medical records because at the times the abnormalities were noted by Lena’s parents, “the paucity of notation in the . . . [medical] records revealed otherwise.” *See* Entitlement Decision at 6.

Moreover, the Special Master is of the opinion that Dr. Schweller failed to adequately address the significance of Lena’s perinatal diagnosis of hydrops fetalis. The Special Master was unpersuaded by Dr. Schweller’s determination that Lena developed normally prior to the

vaccination, because that statement was purportedly based upon Lena's father's account of the facts rather than Lena's medical records. The Special Master was also troubled because Dr. Schweller had apparently relied upon the parents' testimony, rather than the medical records, to conclude that Lena had, at the time of the vaccination, recovered from the viral illness she had suffered in the days immediately leading up to March 31, 1995. *See*, Entitlement Decision at 7. The Special Master also concluded that because Dr. Schweller substantially relied upon Lena's parents' testimony to reach his determination, the analysis by which Dr. Schweller reached the conclusion that there could be "no alternate explanation" for Lena's condition "other than related to the immunization," was flawed. *See* Entitlement Decision at 7. The Special Master says Dr. Schweller's theory is based upon logic rather than causation because it concludes that in the absence of any other rationale, Lena's injuries had to have been caused by the DaPT vaccination. Specifically, the Special Master stated that "[t]here is no sequence of cause and effect showing . . . the reason for Lena's injuries. In fact there is little in the way of a medical theory causally connecting the vaccination and the injury. This [conclusion] is also repeated in Dr. Schweller's second opinion." *See* Entitlement Decision at 7.

With regard to Dr. Schweller's second opinion, the Special Master states that Lena's injuries appear to be idiopathic and that the conclusion that the vaccine caused her injuries is based upon a temporal<sup>9</sup> association which must fail as a basis for causation. In sum, the Special Master asserts that even if the government's medical report were not considered, petitioner's claim for compensation would fail because Dr. Schweller's opinion did not provide or reference any medical literature, did not discuss the findings of the medical community in this area and did not reconcile or explain the facts in the detail required.

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<sup>9</sup>The term "temporal" is a term of art with two possible meanings in the context of litigation pursuant to the Vaccine Act: (1) the literal meaning that the injury occurred subsequent to and close in time to the administration of the vaccine, or (2) the scientific meaning that there is an accepted time frame supported by scientific evidence within which the injury should manifest itself following vaccination. *See Stevens v. Secretary of DHHS*, 2001 WL 387418 n.6 (Fed. Cl. March 30, 2001).

In contrast, the Special Master afforded significant weight to the expert report provided by the government's medical expert, Dr. MacDonald, because of his impressive credentials<sup>\10</sup> and because his expert report was made particularly credible by both his citation to articles written by members of the medical community and his discussion of Lena's early medical history.

The Special Master noted that Dr. MacDonald asserted that petitioner did not establish causation-in-fact and that, in Dr. MacDonald's opinion, it was not clear that Lena suffered an acute encephalopathy as defined medically or on the Table. *See* Entitlement Decision at 10. Moreover, the Special Master recited Dr. MacDonald's conclusion that there was no associated major change documented in her motor status, focal neurological signs or seizure activity, and Lena was neither hospitalized nor treated medically in the two weeks after the immunization. Additionally, the results of Lena's EEG exams, apparently conducted after the vaccination on May 4, 1995, were purportedly normal. *See* Entitlement Decision at 10; *see also* MacDonald Report at 2; Pet'r Ex. 6-55. The Special Master concluded that the government had provided, through expert testimony, sufficient evidence to prove, by a preponderance of the evidence, that there was another cause for Lena's injuries, specifically an autistic condition, which was unrelated to the vaccine. In sum, the Special Master was persuaded by Dr. MacDonald's reliance upon medical literature, which concluded that neonatal complications occur much more frequently in autistic children than in non-autistic children, to assert that the complications Lena suffered at birth were related to the autistic condition she now exhibits.

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<sup>\10</sup>The Special Master asserts that Dr. MacDonald has outstanding credentials and presented a written opinion which the Special Master states he found to be significantly more thorough than that provided by Dr. Schweller. The Special Master writes in laudatory terms about Dr. MacDonald's expert report, noting that "its detail, basis and logic are the hallmark of a credible expert medical witness. His written report was very persuasive. He had a command of his respective field, the existing records in this case, and the facts of the [c]ourt's onset decision attached to this decision." *See* Entitlement Decision at 9.

Based upon his opinion that petitioner's expert report was inadequate, in conjunction with the relative strengths he perceived in respondent's expert report, the Special Master determined that petitioner would be ineligible for compensation pursuant to the Vaccine Act. *See* Entitlement Decision at 8.

Petitioner filed his motion for review, pursuant to Rule 60 of the Rules of the Court of Federal Claims, on May 3, 2002.

**e. Petitioner's Motion for Review**

**(1) The Parties' Contentions**

Petitioner voices numerous objections to the Special Master's Entitlement Decision. First, petitioner asserts that the Special Master failed to give adequate consideration to petitioner's medical expert report and supplemental expert report in comparison with the weight afforded to respondent's medical expert's report. Petitioner disputes certain of Dr. MacDonald's determinations and avers that the government's medical expert inappropriately assumed that the difficulties suffered by Lena at birth were the precursor for the subsequent manifestation of a neurological disorder and autism. Petitioner contends that Lena's perinatal neurological problems were completely resolved long before the DaPT vaccine was administered and are unrelated to the symptoms she exhibited after the immunization. Furthermore, in this regard, petitioner contends that the evidence in this case does not support the Special Master's conclusion that Lena was suffering from a viral infection on the day of the vaccination. Petitioner also avers that the Special Master refused to acknowledge that the government's expert report, which is based upon the theory that Lena's condition is a result of an encephalopathy that occurred at birth, does not comport with evidence contained in the medical records which would support a determination that the encephalopathy suffered at birth was completely resolved, without any residual effects, prior to the administration of the DaPT vaccination.

Second, petitioner protests the factual findings which the Special Master stated were to “stand as the basis of . . . [his decisions filed March 27, 2001, March 29, 2001 and June 29, 2001] and analysis of the medical expert’s reports” are inaccurate and that petitioner’s attempts to redress the inaccuracies through motions for reconsideration were ignored. Moreover, as a result of the application of the purportedly inaccurate statement of facts in this case, the Special Master is alleged to have acted improperly by requiring petitioner to support the allegations pursuant to a causation-in-fact theory, rather than as a Table injury.

Petitioner’s remaining three objections are (1) that the Special Master improperly ignored or denied each of the facts stated in each of petitioner’s two Motions for Reconsideration; (2) that the Special Master failed to demonstrate a thorough review of statements contained in documents filed with the court by petitioner; and (3) that the orders issued by the Special Master in this case were confusing, contradictory and arbitrary.

In response, the government asserted that the Special Master articulated a rational basis for rejecting the expert testimony of petitioner’s expert, Dr. Schweller, and properly assigned greater probative value to the opinion of the government’s expert, Dr. MacDonald. Specifically, respondent asserts that the Special Master based his opinion upon reliable evidence that prior to the immunization, Lena exhibited symptoms specifically related to autism, including poor eye contact and difficulty interacting with outsiders.

Furthermore, respondent asserts that the Special Master did not ignore petitioner’s arguments concerning the facts of this matter, but rather, properly considered each fact presented and was simply not persuaded by petitioner’s version of the facts. Specifically, respondent recites that the Special Master noted that Lena’s parents’ testimony was internally inconsistent and also conflicted with the medical records. Accordingly, respondent asserts that the Special Master acted properly when he attributed greater weight to the medical records than to the parents’ testimony and determined that Lena’s condition stemmed from

neonatal hydrops fetalis and asphyxia, both suffered shortly after birth, rather than from the immunization.

Finally, respondent asserts that the Special Master did not compromise petitioner's opportunity to fully prosecute his case, and that the orders issued in this case were not confusing, but rather, provided detailed instruction to petitioner and his expert.

## ANALYSIS

Jurisdiction is appropriate in this matter pursuant to 42 U.S.C. § 300aa-12(e).

Upon review of a vaccine compensation decision rendered by the Special Masters, this court is empowered by Congress to (1) uphold the findings of fact and conclusions of law sustaining the decision of the Special Master; (2) set aside the Special Master's finding of fact or conclusion of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or (3) remand the petition to the Special Master for further action in accordance with the court's direction. 42 U.S.C. § 300aa-12(e)(2)(A)-(C); *see Saunders v. Secretary of HHS*, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (*quoting Munn v. Secretary of HHS*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see also Davis v. Secretary of DHHS*, 54 Fed. Cl. 230, 233 (2002).

"These standards vary in application as well as degree of deference [and e]ach standard applies to a different aspect of the judgment." *Munn*, 970 F.2d at 870 n.10. Fact findings are reviewed under the arbitrary and capricious standard, legal questions under the "not-in-accordance-with-law" standard, and discretionary rulings are reviewed for abuse of discretion. *Saunders*, 25 F.3d at 1033 (*quoting Munn*, 970 F.2d at 870 n. 10); *Johnson v. Secretary of HHS*, 33 Fed. Cl. 712, 720 (1995), *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (table). The question of discretionary rulings rarely comes into play except in instances in which the Special Master excludes evidence. *Munn*, 970 F.2d at 870 n. 10.

## **Establishing Entitlement to Compensation Pursuant to the Vaccine Act**

The Vaccine Act provides two methods for establishing eligibility for compensation. *See Munn*, 970 F.2d at 865. Petitioner may establish a *prima facie* case by demonstrating that the injuries sustained are listed in the Table,<sup>\11</sup> that the injuries became evident within the time period provided by the Table, and that all other statutory requirements have been met. *Id.*; 42 U.S.C. § 300aa-13(a)(1). If a Table injury can be established, the injuries sustained by petitioner are presumed to have been caused, or significantly aggravated by the vaccine. *See Munn*, 970 F.2d at 865; 42 U.S.C. § 300aa-13(a)(1). A *prima facie* case of entitlement would be considered to be properly presumed in that case. The Secretary may overcome this presumption by demonstrating that a factor unrelated to the vaccine was the actual cause of the injuries sustained. *See* 42 U.S.C. § 300aa-13(a)(1); *see also Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1102 (Fed. Cir. 1996).

Petitioner may still prevail, even if a *prima facie* case cannot be established, by demonstrating, by a preponderance of the evidence, that although the injury did not occur within the time period prescribed by the Table, the vaccination, and not some other agent, actually caused or significantly aggravated the injury. *See Munn*, 970 F.2d at 865.

Under this approach, petitioner must prove, by a preponderance of the evidence, both that, (1) *but for* the DaPT vaccine, Lena Tebcherani would not have suffered her injuries, and (2) that the vaccine was a substantial factor in bringing about the injury. *See Shyface v. Secretary of HHS*, 165 F.3d 1344, 1351-53 (Fed. Cir. 1999). In order to demonstrate that the DaPT vaccine was a substantial factor in bringing about the injury, petitioner must show a reputable medical or scientific

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<sup>\11</sup> With regard to the administration of DaPT, the Table, 42 C.F.R. § 100.3(a) & (b), lists the injuries or conditions and related time periods for the first symptom or manifestation of onset or of significant aggravation after vaccine administration.

theory of cause and effect. *See Knudsen v. Secretary of DHHS*, 35 F.3d 543, 548 (Fed. Cir. 1994); *Hodges v. Secretary of DHHS*, 9 F.3d 958, 960 (Fed. Cir. 1993); *Grant v. Secretary of DHHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). “A proximate temporal association alone does not suffice to show a causal link between the vaccine and the injury.” *Hodges*, 9 F.3d at 960 (*citing Grant*, 956 F.2d at 1148). Nor will “evidence showing an absence of other causes . . . meet petitioner’s affirmative duty to show actual or legal causation.” *Grant*, 956 F.2d at 1149. The Vaccine Act expressly prohibits consideration of “any idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor, injury, illness or condition.” 42 U.S.C. § 300aa-13(a)(2)(A); *Knudsen*, 35 F.3d at 549; *Davis*, 54 Fed. Cl. at 235.

### **On-Table Onset or Significant Aggravation**

For purposes of clarity, petitioner’s claims will be addressed out of the order in which they were presented.

With regard to the findings in the onset determination in this case, the Special Master determined that petitioner failed to establish on-Table onset or significant aggravation due to the absence of proof that Lena displayed symptoms of injury within 72 hours of the DaPT vaccination. *See* 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a).

Petitioner argues that the facts which formed the basis for the Special Master’s decision were inaccurate and that petitioner’s attempts to redress the alleged errors<sup>\12</sup> have been ignored. Petitioner does not state the facts with which there is disagreement, but rather, requests the court to review several documents including the transcript of the

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<sup>\12</sup>Petitioner filed two motions for reconsideration with regard to alleged inaccuracies in the facts found by the Special Master. Both motions were denied by the Special Master. *See* Order filed June 8, 2001; Order filed December 4, 2001. This court does not conduct a *de novo* review of the Special Master’s denial of a motion for reconsideration. *See Sword v. United States*, 44 Fed. Cl. 183, 190 (1999). “Discretionary determinations such as these are left to the individual [, that is, the Special Master,] tasked with conducting the hearing on the petition. . . . which are not reverse[d] . . . absent an abuse of discretion.” *Id.* (*citing Munn*, 970 F.2d 870 n.10).

evidentiary hearing, filed October 6, 1999; petitioner's two motions for reconsideration, of the Special Master's March 27, 2001 decision regarding the onset issue, and reply briefs in response to respondent's opposition, filed April 15, 2001, May 12, 2001 and October 9, 2001; and Orders issued by the Special Master on June 29, 2001 and December 4, 2001.

In opposition, respondent asserts the Special Master's determinations were not arbitrary, capricious or an abuse of discretion. Rather, the government contends the Special Master's findings were based upon an appropriate assessment of the relative weight to be accorded various pieces of evidence. Specifically, respondent asserts that since Lena's parents' testimony was inconsistent and, at times, contradictory, the Special Master acted appropriately by relying upon Lena's medical records. Finally, because the respondent's expert opined that Lena's condition stemmed from neonatal hydrops fetalis and not from the immunization, the government asserts that the Special Master's determination was not derived through arbitrary and capricious means.

In order to prevail upon the Motion for Review and Objections, petitioner must demonstrate that the finding of facts by the Special Master was arbitrary and capricious or constituted an abuse of discretion. As stated above, when the arbitrary and capricious standard is applied to findings of fact, the court does not review the substance of the underlying decision, but rather, considers "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); see *Hines v. Secretary of HHS*, 940 F.2d 1518, 1527 (Fed. Cir. 1991) (citations omitted) (a ruling may be considered 'arbitrary and capricious' if the determination "entirely failed to consider an important aspect of the problem"); *Davis*, 54 Fed. Cl. at 237 (remanding matter for Special Master to assess questions of causation without reference to testimony about SIDS, a disorder of unknown etiology). Nevertheless, the arbitrary and capricious standard is an extremely deferential means of review. *Gurr v. Secretary of HHS*, 37 Fed. Cl. 314, 317 (1997). "If the [S]pecial [M]aster has considered the relevant evidence in the record, drawn plausible inferences and

articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” *Hines*, 940 F.2d at 1528; *see also Gurr*, 37 Fed. Cl. at 317 (“anything short of such a showing is unavailing to appellant and requires that the decision of the Special Master be affirmed”).

With regard to petitioner’s presentation before this court, it is recognized that Mr. Tebcherani is appearing in this action *pro se*, on his daughter’s behalf, and accordingly, the form of his submissions are not held to the same exacting standard as those drafted by an attorney. *Estelle v. Gamble*, 429 U.S. 97 (1976); *Sanders v. United States*, 34 Fed. Cl. 75, 78 (1995), *aff’d*, 104 F.3d 376 (1996); *Reed v. United States*, 23 Cl. Ct. 517, 521 (1991). Accordingly, although a more specific statement of the disputed facts would ordinarily be required by petitioner in his Motion for Review, in recognition of Mr. Tebcherani’s status as a *pro se* petitioner, the enumerated submissions have been reviewed and it is noted that in each of the two motions for reconsideration, petitioner recited substantially the same evidence that petitioner purports is contradictory to the Special Master’s March 27, 2001 determination.

Petitioner’s argument, culled from the various documents cited, is essentially a list of points which purportedly contradict the Special Master’s version of the circumstances of this case. Specifically, petitioner asserts that (1) based upon Lena’s father’s medical records, the strabismus condition was a genetic disorder which was purportedly not an indication of developmental delay. *See* Pet’r Mot. for Recons., filed April 18, 2001, at 2; (2) based upon her parents’ testimony and the medical records, Lena is alleged to have fully recovered from the perinatal hydrops fetalis condition and, by the time she was eighteen months old, was purportedly developing normally and without milestone delays. *See* Pet’r Mot. for Recons., filed April 18, 2001, at 2; Pet’r Mot. for Recons., filed October 12, 2001, at 3-4; (3) based upon the parents’ testimony and corroborative testimony of Dr. Narayan, Lena’s treating pediatrician, Lena was purportedly “completely normal” until the vaccination on March 31, 1995. *See* Pet’r Mot. for Recons., filed April 18, 2001, at 2; Pet’r Mot. for Recons., filed October 12, 2001, at 3-4. In this regard, petitioner asserts that the Special Master improperly stated

in his factual findings, that Lena's development, prior to the March 31, 1995 vaccination, revealed "some normality." *See* Order by Special Master, filed March 27, 2001, at 4; (4) based upon the parents' testimony and the medical records, Lena allegedly was not suffering from a viral infection on the day she received the DaPT vaccination. *See* Pet'r Mot. for Recons., filed April 18, 2001, at 2; Pet'r Mot. for Recons., filed October 12, 2001, at 5; (5) based upon the medical records and the testimony of Dr. Narayan, petitioner asserts that neither of Lena's parents raised concerns about any possible delay in Lena's development prior to the administration of the vaccination. *See* Pet'r Mot. for Recons., filed April 18, 2001, at 3; Pet'r Mot. for Recons., filed October 12, 2001, at 5; (6) Lena's parents' inability to remember the day of the week that Lena was immunized and inaccuracies in their testimony regarding which day Lena went to school, should be attributed to the passage of time and should not be considered as evidence that the parents' testimony is not credible. *See* Pet'r Mot. for Recons., filed April 18, 2001, at 3; Pet'r Mot. for Recons., filed October 12, 2001, at 6-8; (7) to the extent that the Special Master may have continued to have doubts regarding notations in the medical records regarding any alleged delay in Lena's neurological, language or development, petitioner requested the Special Master to seek further clarification. *See* Pet'r Mot. for Recons., filed April 18, 2001, at 3; Pet'r Mot. for Recons., filed October 12, 2001, at 4-5; (8) petitioner also suggested that the Special Master should obtain affidavits of Lena's preschool teachers regarding their assessment of Lena's condition before and after the vaccination. *See* Pet'r Mot. for Recons., filed April 18, 2001, at 3.

With regard to the first contention, that Lena's strabismus condition should not be construed as indicative of developmental delay, it is noted that while there is evidence that Lena suffered from strabismus, there are also indications in the medical records that Lena was noted to exhibit poor eye contact as a separate issue from the strabismus. *See* Pet'r Ex. 6-45, 6-49; Tr. at 104. There is no indication that the Special Master confused or merged the strabismus diagnosis with any other notation in the medical records relative to the pace of Lena's development. Petitioner has not introduced evidence which

would support a determination that the Special Master's determinations were either arbitrary and capricious or an abuse of discretion.

Second, with regard to her parents' assertions that Lena had fully recovered from the perinatal hydrops condition and was developing without milestone delays, the Special Master clearly stated that there was no evidence of seizure activity after the incidents at birth. *See* Onset Decision at 4. Neither Lena's parents nor the Special Master are medical specialists. Accordingly, the Special Master relied upon statements of experts about the relevance of events in the medical records. The court can discern nothing arbitrary, capricious or unlawful about that reliance. Similarly, the Special Master's notation that prior to the vaccination, there was "some normality," is not, as alleged in the third item enumerated above, arbitrary and capricious, rather, it is a broad observation which reflects that Lena did suffer some medical difficulties and comports with Dr. Narayan's testimony that the medical records "document[ed] . . . delays in [Lena's] motor development, which consisted of things like rolling over, sitting up, walking." Tr. at 88; *see also*, Onset Decision at 4.

Furthermore, it is undisputed that, as petitioner asserts in the fifth item enumerated above, Dr. Narayan did testify at the October 27, 1994 hearing, that Lena's parents did not have specific concerns regarding her quiet demeanor or any signs of developmental delay. Tr. at 90, 107. Notwithstanding petitioner's assertions to the contrary, the Special Master did not fail to consider all the evidence on this point. Lena's parents may not have noticed developmental delays however, the contemporaneous medical records, as well as Dr. Narayan's testimony, are significant for the reference to developmental delays. Pet'r Ex. 6-21; 6-45. The Special Master acted within his discretion when he chose to give greater weight to the contemporaneous medical records than to recollection testimony offered by Lena's parents. *See Cucuras v. Secretary of HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("[m]edical records in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions"); *Giles v. Secretary of DHHS*, 37 Fed. Cl. 525, 540-41 (1997), *aff'd*, 168 F.3d

1316 (Fed. Cir. 1998) (table); *see also Arrowood v. Secretary of DHHS*, 28 Fed. Cl. 453, 458 (1993) (“[a] record created in the normal course by . . . the family physician should receive more weight than oral testimony given years after the event”). Accordingly, for the reasons stated above, the Special Master’s suggestion that Lena exhibited developmental delays prior to the administration of the vaccine, is not reversible error.

However, with regard to Lena’s parents’ fourth enumerated concern, that the Special Master improperly concluded that Lena was suffering from a viral infection on the day of the vaccination, it is noted that the Special Master specifically stated that there was insufficient evidence to determine whether Lena suffered from a viral infection on March 31, 1995. *See* Onset Decision at 4. After mentioning the fact, the Special Master concluded that he could not make any finding whatsoever upon the issue. *See* Onset Decision at 4. Inexplicably, later in the same order, the Special Master repeated the language from Lena’s father’s testimony regarding this viral illness, but with the express notation that it would be speculative for him to make any determination about whether “the illness prior to vaccination had actually cleared itself up.” *See* Onset Decision at 6. In the Entitlement Decision, the Special Master again referred to this viral illness, after noting that petitioner’s medical expert, Dr. Schweller, had “rul[ed] out the viral illness.” *See* Entitlement Decision at p. 7. However, the Special Master went further than he had in his Onset Decision and stated that “[w]hat this [viral] illness was is unknown but we are certain that it did exist. Probative here is that there is no support in the records that this illness resolved itself; that is to say, it is unclear whether the illness ever resolved. This is Petitioner’s burden.” *See* Entitlement Decision at p. 7.

Although in his Onset Decision the Special Master tempered the effect of his presumptions about the viral illness that Lena endured prior to administration of the vaccine, by noting that any findings of fact on the matter would be speculative, the repeated references to that sickness, both with and without the qualifying language explaining why that evidence was not conclusive, constituted an unreasonable inference that the virus may have been somehow related to Lena’s injuries. It was

arbitrary and capricious for the Special Master to repeatedly discuss that fact in such a manner after having determined that any conclusions drawn therefrom would necessarily constitute unsubstantiated speculation.

It is well established that the appropriate standard to use in determining whether there was a reasonable basis for asserting a Table injury is one analogous to that used in deciding motions for summary judgment, that is that any inferences from the evidence presented shall be drawn in the light most favorable to the petitioner. *See Jay v. Secretary of DHHS*, 998 F.2d 979, 982 (Fed. Cir. 1993); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). After noting that he did not have sufficient evidence to determine whether the virus had any impact upon the injuries Lena suffered after the vaccination, the Special Master should have declined to comment again upon the issue. Repeated references to the virus, without any supportive facts constituted an inference that was unfavorable to Lena, particularly since Dr. Schweller had ruled out the viral illness as a causative factor and Dr. MacDonald similarly declined to comment upon that disease at all except to state that Lena suffered a viral illness during the spring of 1994.<sup>\13</sup>

Moreover, the Special Master appears to have imposed an inappropriate burden upon petitioner by apparently requiring proof beyond the stated observations of her parents, to show that any viral illness Lena may have suffered was resolved before the vaccine was administered. *See*, Entitlement Decision at 7. The law places the burden upon the government, in seeking to defeat a petitioner's claim with a theory of viral infection, to prove "that there was in fact a viral infection in the particular case [which was] . . . principally responsible for *causing* the petitioner's illness, disability, injury, condition or death. *Knudsen*, 35 F.3d at 549 (*quoting* 42 U.S.C. § 300aa-13(a)(2)) (emphasis in original); *see also Giles*, 37 Fed. Cl. at 537-38, *aff'd* 168 F.3d 1316 (Fed. Cir. 1998) (table). This burden belongs to the government, not to the petitioner. "The Vaccine Act . . . expressly recognizes that a child may

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<sup>\13</sup>It is unclear from this statement whether Dr. MacDonald is referring to symptoms of a viral illness suffered before or after the vaccination.

have an infection at the time of vaccination and injury and still recover—this situation occurs where the government does not prove that the ‘infection’ was ‘principally responsible for causing’ the injury complained of.” *Knudsen*, 35 F.3d at 550.

Nevertheless, this court is constrained to find those errors to be harmless in this case, because neither the Special Master’s inappropriate reference to the presence of an alleged viral illness nor the improper assignment of the burden of proof impacted the ultimate decision in this matter. *Johnson*, 33 Fed. Cl. at 727-28, *aff’d*, 99 F.3d 1160 (Fed. Cir. 1996) (table). Even assuming that the presumption that Lena experienced a Table injury had been established, compensation might still be properly denied upon a showing, by a preponderance of the evidence, that Lena’s condition was caused by “factors unrelated” to either the administration of the vaccine or the alleged viral illness. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *see also Cucuras*, 993 F.2d at 1528; *Davis*, 54 Fed. Cl. at 235. In this case, the Special Master did not rule that the viral illness caused Lena’s injuries, rather, he determined that he found the government’s expert witness, Dr. MacDonald, to be more persuasive. Dr. MacDonald’s conclusions were not driven by the Special Master’s inferences regarding the alleged viral illness, but rather that Lena’s autism was caused by incidents suffered at birth which, he concluded, led to a lifetime of developmental delay. Although the Special Master’s erroneous inferences on this subject were ultimately harmless, it is important to note that evidence of a viral infection alone would ordinarily be insufficient to prove that a factor unrelated to the vaccine caused the injury. *Knudsen*, 35 F.3d at 550.

Finally, petitioner asserts, in the sixth, seventh and eighth items enumerated above, that Lena’s parents’ failure to remember the day of the week upon which Lena was vaccinated should not be construed as casting a shadow of implausibility over their testimony. In connection with this assertion, petitioners’ contend that the Special Master failed to sufficiently ventilate the facts by investigating the meaning of certain arguably questionable notations in the medical records and to inquire of Lena’s preschool teachers regarding their recollection of Lena’s behavior before and after the vaccine was administered.

In this regard, it is noted that at the October 6, 1999 hearing, the Special Master discounted the credibility of Lena's parents' testimony, in part, because of inconsistencies regarding the days of the week that Lena attended school. The Special Master has discretion to determine the credibility of witnesses. *Bradley v. Secretary of DHHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (finding determinations of fact by Special Master to be 'virtually unreviewable' due to the broad discretion afforded as fact-finders in determining credibility and because as fact-finder, Special Master has first hand knowledge of witnesses and their testimony); *see also Epstein v. Secretary of DHHS*, 35 Fed. Cl. 467, 478 (1996) (noting that Vaccine Act prohibits Special Master from relying solely on uncorroborated parental testimony to award compensation). Nevertheless, with regard to the testimony elicited in this case, at the October 6, 1995 hearing, the Special Master strongly inferred that if he had a means of verifying Mrs. Tebcherani's testimony with regard to the dates that Lena attended school, he might have been able to establish that Lena exhibited an onset of her injuries within the 72 hour time frame necessary to demonstrate a Table injury. Tr. at 119. At that hearing, copies of Lena's attendance records were introduced which demonstrated that she did not have a recorded absence on Monday, April 3, 1995, which would have been within 72 hours of the vaccination on March 31, 1995. The school records were subsequently filed with the Special Master on November 1, 1999. *See* Pet'r Ex. 19; Tr. at 56-57.

Notwithstanding his earlier statement that the conflicting testimony offered by Lena's parents was problematic with regard to the issue of determining the timing of the onset of Lena's symptoms, the Special Master ignored the school attendance records when he "affirmed" the findings stated during the October 6, 1999 hearing. *See* Onset Decision at 3. In this regard, the Special Master abused his discretion by excluding from his review the very evidence he stated was necessary to assist in determining the timing of the onset of injury. The school records are relevant evidence which would likely support the timing of the onset of Lena's injuries. Furthermore, in the absence of a medical evaluation during the first 72 hours following the vaccination, the school records may be valuable for purposes of leading to the discovery of additional fact witnesses employed by Lena's school, who

may be able to describe Lena's condition on Monday, April 3, 1995, which the Special Master pointed out, was "right on the edge [of] . . . 72 hours" after Lena received the DaPT vaccination. Tr. at 119.

Notwithstanding petitioner's motion for review of the Special Master's conclusions, the significance of Lena's attendance records and the possibility that the Special Master had apparently overlooked these potentially important documents, was first noted by this court in the Order remanding the matter to the Special Master, after this court recognized that in stating his conclusions regarding the evidentiary hearing, the Special Master had criticized Lena's parents' testimony as being contradictory on this point. Tr. at 118-22. Notwithstanding the court's clearly articulated suggestion, contained in the March 21, 2001 Order, that the Special Master should review the attendance records, in his decision regarding onset, the Special Master again criticized Lena's parents based upon conflicting testimony regarding the day of the week that Lena attended school. *See* Order filed March 21, 2001 at 20, n. 10; *see also* Onset Decision at 4-5. It is further noted that the point was raised a second time by Dr. Schweller, in his first expert report, by his suggestion that further evidence might be available from fact witnesses that would either support or defeat Lena's parents' testimony. *See* Order filed March 21, 2001 at 20, n. 10; Schweller Report # 1 at 5.

The Special Master's failure to address any impact that the school records might have had upon the testimony precluded an informed review and accordingly constitutes an abuse of discretion in this matter. This is particularly so in light of the fact that in stating his conclusions regarding the evidentiary hearing, the Special Master criticized Lena's parents' testimony as being contradictory on this point but then disregarded documentary evidence when it was made available to the court. Tr. at 118-22. It has previously been acknowledged that the Special Master is not required to be a "potted plant" during the investigation of vaccine claims. *Hines v. Secretary of DHHS*, 21 Cl. Ct. 634, 648 (1990), *aff'd*, 940 F.2d 1518 (Fed. Cir. 1991). "Rather, the legislative history of the . . . Vaccine Act emphasizes that "[t]he system is intended to allow the proceedings to be conducted in . . . an 'inquisitional' format, with the (special) [sic] master conducting

discovery (as needed), cross examination (as needed) and investigation.”” *Id.* at 648-49 (*citing* 135 Cong. Rec. H9476 (daily ed. Nov. 21, 1989)). Accordingly, the case must be remanded for further findings on the issue of the timing of the onset of Lena’s injuries.

As stated above, a failure to consider this evidence might be considered harmless error if it could be shown that the failure would not have made any difference with regard to the outcome of the case. *See e.g., Johnson*, 33 Fed. Cl. at 728-29, *aff’d*, 99 F.3d 1160 (Fed. Cir. 1996) (table). It is premature to say whether the attendance records would lead to dispositive evidence regarding the onset or aggravation of Lena’s injuries.

Moreover, on the issue of Lena’s current diagnosis, the experts are in apparent agreement that she exhibits characteristics of autism. Moreover, both experts state that parents and pediatricians often do not recognize the early symptoms of abnormalities such as those Lena suffered in this instance. Schweller Report #1 at 5; Schweller Report #2 at 3; MacDonald Report at 4. The effect of certain elements of certain vaccinations, including the DPT vaccine, upon individuals who exhibit autistic behaviors has been the subject of other suits before the Special Masters. *See Lassiter v. Secretary of DHHS*, 1996 WL 749708 (Dec. 17, 1996) (determining that respondent’s assertion that child may have suffered from autism prior to administration of DPT vaccination was insufficient to overcome presumption of a Table injury in absence of a conclusive diagnosis of autism or other metabolic disturbance prior to vaccination); *see also Waddell v. Secretary of DHHS*, 1990 WL 293870 (December 2, 1990) (concluding that because cause of autism was of unknown etiology, such a diagnosis would be insufficient to establish an alternative cause for petitioner’s condition, but when considered along with uncertainties as to actual onset of symptoms, would also cast sufficient doubt to militate against a finding for petitioner).

By Order filed July 3, 2002, the Office of the Special Masters expressly addressed these cases by allowing for a period of examination to determine whether the elements of certain vaccines, might cause or aggravate autistic conditions in some children. *See Claims for Vaccine*

*Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder Various Petitioners v. Secretary of Health and Human Services* (“Autism General Order #1”), 2002 WL 31696785 (Fed. Cl., Spec. Mastr. July 3, 2002) (noting that there is ongoing research to determine whether there exists evidence of medical and legal causation sufficient to support program claims). That order was issued in response to the “concern in recent years that certain childhood vaccinations might be causing or contributing to an apparent increase in the diagnosis of a type of serious neurodevelopmental disorder known as ‘autism spectrum disorder’ or ‘autism.’” *Id.* at \*1.

As stated above, the Special Master noted that issues of causation may be impacted by the “progress of medical science.” *See* Entitlement Decision at 5. This case is an excellent example of that observation. The facts of the autistic symptoms and the sudden worsening of those symptoms after the vaccine should have led the Special Master to the conclusion that Lena may be suffering from a significant aggravation of a pre-existing autistic condition. *See Whitecotton*, 81 F.3d at 1107 (setting forth standards for determining whether petitioner has successfully demonstrated a *prima facie* Table significant aggravation claim pursuant to Vaccine Act); *see also Gruber v. Secretary of DHHS*, 1998 WL 928423 (Fed. Cl. Spec. Mastr. Dec. 22, 1998)

On remand, the Special Master must address the questions of whether evidence of autism, in combination with evidence of the onset of symptoms, is sufficient to demonstrate significant aggravation of the autistic condition and whether Lena’s case may be appropriate for consideration pursuant to the procedures set forth pursuant to the Vaccine Program. In this regard, the Special Master should consider the petition to be amended to conform with the proof already presented in this matter and address the question of whether the vaccination caused or significantly aggravated Lena Tebcherani’s injuries in accordance with the procedures set forth in General Autism Order #1.

Moreover, to the extent that the Special Master’s decision was based upon facts which excluded the school records and any facts which might necessarily flow from a thorough investigation of the implication

of those facts, on remand he should correct the error and assess the impact of the school records upon his determination regarding Mrs. Tebcherani's credibility. The permissive scope of the Special Master's inquiry is virtually unlimited. *Whitecotton*, 81 F.3d at 1108-09. If additional testimony is necessary from any of the witnesses, or from third parties the Special Master should act within his discretion to obtain such testimony.

### **Actual Causation or Significant Aggravation**

The Special Master concluded, based upon weaknesses he perceived in Dr. Schweller's medical expert report, that petitioner failed to prove that the DaPT vaccine actually caused Lena's condition. The Special Master asserted that petitioner's expert's opinion was so inadequate that even without considering respondent's expert's opinion, he would be predisposed to deny compensation. Moreover, the Special Master found respondent's expert report was sufficiently persuasive to defeat petitioner's assertions in this matter.

Petitioner strongly objects to the disparity in weight the Special Master gave to petitioner's expert in comparison with that afforded to respondent's expert. In opposition, respondent asserts this allegation is unfounded and that in any case, it was reasonable for the Special Master to find Dr. MacDonald's opinion more persuasive.

As a preliminary matter, this Court does not generally have authority to re-weigh evidence presented and ruled upon by the Special Master, even if this court might have considered the significance of the expert testimony differently. *See Johnson*, 33 Fed. Cl. at 725-26, *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (table); *Bradley*, 991 F.2d at 1575; *Munn*, 970 F.2d at 871. In the absence of evidence that the Special Master's actions were arbitrary and capricious, this court has little option than to uphold his findings. *See Johnson*, 33 Fed. Cl. at 725-26, *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (table); *Munn*, 970 F.2d at 871. Nevertheless, to the extent the Special Master relies upon expert testimony, such testimony must be reliable, since an expert opinion can be no better than the soundness of the reasoning supporting it. *Perreira v. Secretary of DHHS*, 33 F.3d 1375, 1377 n. 6 (Fed. Cir. 1994) (citations omitted).

Petitioner points to conclusions in each of the expert reports which he asserts are incorrect and thus unreliable. First, petitioner attacks Dr. MacDonald's opinion that Lena demonstrated a subtle progression of symptoms over the course of her lifetime. Petitioner asserts that although Lena did suffer seizures at birth, the medical records demonstrate that her condition was wholly resolved and that she did not suffer autistic symptoms prior to the immunization. In support, petitioner cites to excerpts from medical records created before Lena was two years old. The medical records reflect that the results of the EEG conducted on November 19, 1990, before Lena was a month old, were mildly abnormal. Pet'r Ex. 4-9; 6-9. Essentially, petitioner asserts that Dr. MacDonald's testimony is not credible because he did not mention the medical records created before Lena was two months old and did not find, as petitioner asserts he should have, that Lena had fully recovered from the neonatal hydrops fetalis and asphyxia.

As stated above, credibility determinations are virtually unreviewable. See *Johnson*, 33 Fed. Cl. at 725-26, *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (table); *Bradley*, 991 F.2d at 1575; *Munn*, 970 F.2d at 871. The Special Master is responsible for weighing the testimony and other evidence and drawing reasonable inferences. This court does not substitute its own judgment for that of the Special Master when he has considered and weighed the evidence presented. *Johnson*, 33 Fed. Cl. at 725-26, *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (table). Additionally, in this case, Dr. MacDonald identified symptoms of Lena's alleged autism which became evident sometime after Lena was two months old. Even if it was an error for Dr. MacDonald to fail to mention the determinations by some of her treating physicians, that by the time Lena was two months old she had recovered completely from the hydrops fetalis condition and associated asphyxia, this lapse was not central to Dr. MacDonald's conclusions. Rather, Dr. MacDonald pointed to symptoms which arose between the time Lena was two months old and her vaccination and concluded that, in hindsight and based upon relevant medical literature, Lena's autism was more likely than not related to those perinatal events. Dr. MacDonald's reasoning is sound. Therefore, the Special Master's

evaluation and reliance upon Dr. MacDonald's expert opinion in this matter was neither arbitrary, capricious, nor an abuse of discretion.

Second, petitioner asserts that petitioners' expert, Dr. Schweller, did not rely solely upon Lena's parents' testimony, to reach his conclusions. Instead, petitioner asserts that Dr. Schweller relied upon the parents' testimony in conjunction with the medical records. Petitioner is essentially averring that Dr. Schweller's expert testimony should be afforded more credibility than the Special Master allowed. As stated earlier, credibility determinations are virtually un-reviewable. *See Johnson*, 33 Fed. Cl. at 725-26, *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (table); *Bradley*, 991 F.2d at 1575; *Munn*, 970 F.2d at 871. Although the Special Master does quote Dr. Schweller's determination that the outcome of the case "depends completely on the acceptance or rejection of the history as provided by the family," there is no indication that the Special Master determined that Dr. Schweller failed to rely upon the medical records. *See Entitlement Decision* at 7-8. Rather, the Special Master specifically criticized Dr. Schweller based upon the fact that he did rely upon medical records in conjunction with the parental testimony. *See Entitlement Decision* at 7-8.

Dr. MacDonald is the only person who has stated that Dr. Schweller's theory of causation seemed to rely solely on the parents' history. *See MacDonald Report* at 5. The Special Master is not bound to follow the opinion of an expert witness. *See* 42 U.S.C. § 300aa-13(b)(1); *Johnson*, 33 Fed. Cl. at 726, *aff'd*, 99 F.3d 1106 (Fed. Cir. 1996) (table). The Special Master has not incorporated this portion of Dr. MacDonald's opinion into his ultimate determination. Accordingly, the Special Master's evaluation of the expert opinions in this matter was neither arbitrary, capricious, nor an abuse of discretion.

Petitioner's final objection with regard to the experts' opinions is a complaint that the Special Master made several complimentary statements with regard to his description of the quality of Dr. MacDonald's assessment and expert report, but that he disparaged Dr. Schweller's expert report. Essentially, petitioner's argument is, again, that the expert testimony in this case should have been weighed differently. Ultimately, the Special Master's conclusions amount to an

explanation of his own opinion that Dr. Schweller's opinions are less persuasive than those offered by Dr. MacDonald. The Special Master's decision as to how much weight to give expert testimony is entitled to substantial deference by the court. *Johnson*, 33 Fed. Cl. 712, 726 (1995) ("questions concerning the weight given to evidence are within the special master's purview"), *aff'd*, 99 F.3d 1106 (1996) (table). Given the deference this Court must show the Special Master's determinations of weight with regard to evidence, it is concluded that the Special Master's evaluation was neither arbitrary and capricious, nor an abuse of discretion.

As noted earlier, based upon the experts' agreement that Lena exhibits symptoms of autism, this case presents questions as to whether she experienced a significant aggravation of a potentially pre-existing autistic condition which might be linked to the March 31, 1995 administration of the DaPT vaccination. In the event that, upon consideration of all the evidence available upon remand, a *prima facie* case of significant aggravation cannot be established, additional expert opinions will be necessary to address the question of whether the vaccination caused any significant aggravation of any autistic condition with which Lena may have been suffering prior to immunization. *See e.g. Lampe v. Secretary of HHS*, 219 F.3d 1357, 1366-67 (Fed. Cir. 2000) (reviewing decision by Special Master regarding expert opinions as to whether DPT vaccination significantly aggravated potentially pre-existing condition); *see also Hoag v. Secretary of HHS*, 42 Fed. Cl. 238, 247 (1998) (noting that a second round of expert opinions and another evidentiary hearing were held to deal with the issue of significant aggravation).

Finally, the court finds no merit in petitioners' assertions that the Special Master did not demonstrate a thorough review of the documents filed by petitioner in this matter. The administrative error to which petitioner refers with regard to the clerical errors was rectified prior to the entry of judgment and did not impact the determination in this matter. *See Patton v. Secretary of DHHS*, 25 F.3d 1021 (Fed. Cir. 1994) (determining that after Clerk of Court enters judgment in accordance with Special Master's decision, a Special Master may not re-assert

jurisdiction to amend that decision). It is unfortunate that the mistakes were not rectified before the order was issued, however, petitioner has not provided any basis upon which an assertion that the merits of the decision were not carefully addressed might succeed.

Moreover, to the extent that petitioner finds the orders issued by the Special Master in this matter to be confusing, it is suggested that although petitioner certainly has a right to proceed in this matter on a *pro se* basis, it would be prudent to seek the assistance of professional legal counsel in order to alleviate any further confusion in proceedings in this matter.

### CONCLUSION

Accordingly, it is **ORDERED** that:

(1) The Special Master's decision upon the facts of this matter petitioner's entitlement to compensation pursuant to 42 U.S.C. § 300aa-14 and 42 C.F.R. § 100.3(a) is **SET ASIDE**;

(2) This matter is hereby **REMANDED**, pursuant to 42 U.S.C. § 300aa-12(e)(2)(C) for further proceedings consistent with this Order.

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James F. Merow  
Senior Judge